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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,009

05/03/2005

Ruth Chiquet-Ehrismann

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HOXIE & ASSOCIATES LLC
75 MAIN STREET , SUITE 301
MILLBURN, NJ 07041

EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,009	Applicant(s) CHIQUET-EHRISMANN ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-52, 58-60 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 14-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-60 and 65-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> |

DETAILED ACTION

1. Claims 11-13, 53-57, 61-64 and 69-72 are cancelled.

Claim 65 has been amended.

Claims 1-10 and 14-52 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 27, 2007.

2. Claims 58-60 and 65-68 are under examination.

3. The following office action contains NEW GROUNDS of Rejection.

4. The examiner apologizes for any confusion between the office action dated October 10, 2007 and the office action dated April 7, 2008. Claims 58, 59, and 65-67 were incorrectly identified as being in condition for allowance in the October 10, 2007 office action.

Rejections Withdrawn

5. The rejection of claims 58-60 and 65-68 under 35 U.S.C. 102(e) as being anticipated by Ni, et al. is withdrawn in view of applicant's arguments.

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6. The rejection of claims 58, 65, and 66 under 35 U.S.C. 103(a) as being obvious over Weber, et al. in view of Campbell is withdrawn in view of applicant's arguments and amendment to claim 65.

NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66-68 are indefinite in the recitation "three C-terminal fibronectin III repeats in the region defined by..." the recited amino acid residues in claim 66. The phrase is indefinite because the exact meaning of the phrase is unclear and the term "defined" according to the Merriam-Webster online dictionary (www.m-w.com/dictionary.htm) means to determine or identify the essential qualities or meaning of, or to fix or mark the limits of. Thus, it is unclear if the recited amino acid residues of SEQ ID No. 4 define the sequences of the amino acid residues and are a required element of the claims or if the recited amino acid residues merely define the boundaries of the region. Accordingly, the phrase "three C-terminal fibronectin III repeats in the region defined by..." renders the claim indefinite because it is unclear whether the

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limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 58-60 and 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Morris, et al. (US PG PUB 2002/0182586, filed March 1, 2002).

The claims recite an isolated antibody that specifically recognizes amino acids 791-1054 of the polypeptide having the amino acid sequence shown SEQ ID NO: 4, for the manufacture of a medicament, wherein said medicament is for the treatment of breast cancer. The claims also recite an isolated antibody that specifically recognizes one or more of the three C-terminal fibronectin III repeats of mammalian tenascin W, wherein said antibody specifically recognizes one or more of the three C-terminal fibronectin III repeats in the region defined by amino acids 791-1054 of the tenascin W polypeptide having the amino acid sequence shown SEQ ID NO: 4, for the manufacture of a medicament, wherein said medicament is for the treatment of breast cancer.

Regarding the indefiniteness of claims 66-68, for the purposes of this rejection the claims are being interpreted to mean that the antibody binds to amino acids 791-1054 of SEQ ID No. 4.

Morris, et al. teach an antibody to a protein that is 99.8% identical to the polypeptide of SEQ ID No. 4 (tenascin W) and 99.2% identical to amino acids 791-1054 of SEQ ID No. 4 (see sequence alignment). Morris, et al. teach the protein is associated with carcinomas, especially lymphoma, breast cancer or prostate cancer (paragraph 18) and the antibody is useful for immunotherapy (thus a medicament, see paragraph 106). The product of the claims is defined in terms of a laboratory designation rather than by physical characteristics, structure or even the process by which the product is prepared. Consequently, comparison of this product with the prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Thus a lesser burden of proof is required to make out a case of anticipation for a product claimed in terms of a laboratory designation than when claimed in conventional fashion by its physical characteristics, structure or even in terms of the process by which it is made.

Therefore, it is the Examiner's position that Morris, et al. have produced antibodies that are directed to the same antigen that the claimed antibodies bind and in turn, antibodies that bind to amino acids 791-1054 of SEQ ID No. 4. One of ordinary skill in the art would reasonably conclude that Morris' antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Morris has produced antibodies that are identical to the claimed antibody.

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Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Morris, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

October 7, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643